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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---|-------------------|----------------------|---------------------|-----------------|
| 10/633,771 | 08/04/2003 | Eric Vivier | INN-113TD2 | 6493 |
| 23557 | 7590 04/03/2006 | | EXAMINER | |
| SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION | | | SISSON, BRADLEY L | |
| PO BOX 142 | | | ART UNIT | PAPER NUMBER |
| GAINESVIL | LE, FL 32614-2950 | | 1634 | |

DATE MAILED: 04/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | Application No. | Applicant(s) | | | | |
|--|---|---|--------|--|--|--|
| | 10/633,771 | VIVIER ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Bradley L. Sisson | 1634 | | | | |
| The MAILING DATE of this communication a Period for Reply | ppears on the cover sheet w | ith the correspondence add | dress | | | |
| A SHORTENED STATUTORY PERIOD FOR REP WHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory perior - Failure to reply within the set or extended period for reply will, by statu Any reply received by the Office later than three months after the main earned patent term adjustment. See 37 CFR 1.704(b). | DATE OF THIS COMMUNI 1.136(a). In no event, however, may a number of will apply and will expire SIX (6) MONute, cause the application to become Al | CATION. reply be timely filed ITHS from the mailing date of this co BANDONED (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on | | | | | | |
| · _ · · · · · · · · · · · · · · · · · · | nis action is non-final. | | | | | |
| · <u> </u> | • | | | | | |
| | closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4)⊠ Claim(s) <u>24-71</u> is/are pending in the applicat | ion. | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5) Claim(s) is/are allowed. | | | | | | |
| 6) Claim(s) is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) 24-71 are subject to restriction and | or election requirement. | | | | | |
| Application Papers | | | | | | |
| 9)☐ The specification is objected to by the Exami | ner. | | | | | |
| 10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the | Examiner. Note the attache | d Office Action or form PT | O-152. | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. | | | | | | |
| 2. Certified copies of the priority docume3. Copies of the certified copies of the prapplication from the International Bure | iority documents have beer | | Stage | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| | | | | | | |
| Attachment(s) | | | | | | |
| Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948) | | Summary (PTO-413) s)/Mail Date | | | | |
| Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date | | nformal Patent Application (PTC | -152) | | | |

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Supplemental Office Action

1. The following is a Supplemental Office Action to that mailed 14 March 2006. The period for response is reset with the mailing of the instant Office action.

Election/Restrictions

- 2. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 24, 26-34, 37-45, 48, and 50-69, drawn to a method of identifying repertoire of NKR inhibitory receptors in a subject, classified in class 435, subclass 6.
 - II. Claims 25-32, 35-45, 49-56, and 61-69, drawn to a method of identifying repertoire of NKR activatory immunoreceptors within a subject, classified in class 435, subclass 6.
 - III. Claims 46, 47, 70, and 71, drawn to a kit, classified in class 536, subclass 24.33.
- 3. The inventions are distinct, each from the other because of the following reasons:
- 4. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions are drawn to different methods that are comprised of different method steeps and which result in different end products.
- 5. Inventions III and I-II are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product

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as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the product as claimed can be used in a materially different process of using that product, such as the methods of Group I or the method of Group II.

- 6. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, and because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 7. This application contains claims directed to the following patentably distinct species: In the event that applicant elects the invention of Group I, applicant is required to elect one of the following species for examination:
 - a. Claims 33 and 57, method used to document genotypic repertoire of KIR immunoreceptors;
 - b. Claims 34 and 58, method used to document the expression repertoire of KIR immunoreceptors.
 - c. Claims 35 and 59, method is used to document the genotypic repertoire of KAR immunoreceptors.
 - d. Claims 36 and 60, method is used to document expression repertoire of KAR immunoreceptors.
 - e. Claims 40 and 64, method used to predict or monitor acceptance or rejection, by a subject, of cells, tissue, or organ.
 - f. Claims 41 and 65, method used to predict or to monitor safety or pathogenicity (GVH), for a subject, of a graft or transplant, of cells, tissue, or organ.

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- g. Claims 42 and 66, method used to predict or to monitor for a subject of a GVL-type effect on the part of cells, tissue or organ, which are genetically different.
- h. Claims 43 and 67, method used to determine the state of activation of NK and/or T cells within a subject.
- i. Claims 44 and 68, method used to predict or monitor the state of resistance of a subject to (i) infection, (ii) autoimmune disease, or (iii) development of malignant cells.
- j. Claims 45 and 69, method used to screen for compositions that are used to reduce the symptoms associated with infectious autoimmune or proliferative disorders.
- 8. The species are independent or distinct because the species are all drawn to different methods that result in different end products.
- In the event that applicant elects the invention of Group Π , applicant is required to elect one of the following species for examination:
 - a. Claims 35 and 59, method used to document genotypic repertoire of KAR immunoreceptors.
 - b. Claims 36 and 60, method used to document the expression repertoire of KAR immunoreceptors.
 - c. Claims 40 and 64, method used to predict or monitor acceptance or rejection, by a subject, of cells, tissue, or organ.
 - d. Claims 41 and 65, method used to predict or to monitor safety or pathogenicity (GVH), for a subject, of a graft or transplant, of cells, tissue, or organ.
 - e. Claims 42 and 66, method used to predict or to monitor for a subject of a GVL-type effect on the part of cells, tissue or organ, which are genetically different.

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- f. Claims 43 and 67, drawn to use of method to determine the state of activation of NK and/or T cells within a subject.
- g. Claims 44 and 68, method used to predict or monitor the state of resistance of a subject to (i) infection, (ii) autoimmune disease, or (iii) development of malignant cells.
- h. Claims 45 and 69, method used to screen for compositions that are used to reduce the symptoms associated with infectious autoimmune or proliferative disorders.
- 10. The species are independent or distinct because the species are all drawn to different methods that result in different end products.
- 11. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 24, 26-32, 37-39, 48, 50-56, and 61-63 generic with respect to Group I; and claims 25-32, 37-39, 49-56, and 61-63 are generic with respect to Group II.
- Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.
- Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

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14. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37)

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CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

- 15. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.
- 16. Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.
- 17. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).
- 18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

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19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

20. Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR

system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bradley L. Sisson **Primary Examiner**

B. L. Linor

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BLS

29 March 2006